

Medication Guide
QUILLIVANT™ XR (\kwil-ə-vant\)
(methylphenidate hydrochloride)
for extended-release oral suspension CII

Read this Medication Guide that comes with QUILLIVANT XR before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with QUILLIVANT XR.

What is the most important information I should know about QUILLIVANT XR?

The following have been reported with use of methylphenidate hydrochloride and other stimulant medicines.

1. Heart-related problems:

- **sudden death in patients who have heart problems or heart defects**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting QUILLIVANT XR.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with QUILLIVANT XR.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking QUILLIVANT XR.

2. Mental (Psychiatric) problems:

All Patients

- **new or worse behavior and thought problems**
- **new or worse bipolar illness**

Children and Teenagers

- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

Tell your doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking QUILLIVANT XR, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is QUILLIVANT XR?

QUILLIVANT XR is a central nervous system stimulant prescription medicine. QUILLIVANT XR is a liquid medicine that you take by mouth. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).** QUILLIVANT XR may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

QUILLIVANT XR should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

QUILLIVANT XR is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep QUILLIVANT XR in a safe place to prevent misuse and abuse. Selling or giving away QUILLIVANT XR may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

It is not known if QUILLIVANT XR is safe and effective in children under 6 years of age.

Who should not take QUILLIVANT XR?

QUILLIVANT XR should not be taken if you or your child:

- are allergic to methylphenidate hydrochloride, or any of the ingredients in QUILLIVANT XR. See the end of this Medication Guide for a complete list of ingredients in QUILLIVANT XR.
- are taking or have taken within the past 14 days an antidepressant medicine called a monoamine oxidase inhibitor or MAOI.

QUILLIVANT XR may not be right for you or your child. Before starting QUILLIVANT XR tell your or your child's doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- are pregnant or plan to become pregnant. It is not known if QUILLIVANT XR will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breast feed. QUILLIVANT XR passes into your breast milk. You and your doctor should decide if you will take QUILLIVANT XR or breast feed.

Tell your doctor about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements.

QUILLIVANT XR and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking QUILLIVANT XR.

Your doctor will decide whether QUILLIVANT XR can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- anti-depression medicines including MAOIs
- cold or allergy medicines that contain decongestants

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while taking QUILLIVANT XR without talking to your doctor first.

How should QUILLIVANT XR be taken?

- Take QUILLIVANT XR exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.

- Take QUILLIVANT XR once each day in the morning. QUILLIVANT XR is an extended-release suspension. It releases medicine into your body throughout the day.
- QUILLIVANT XR should be used with the oral dosing dispenser provided with the product. If the oral dosing dispenser is missing or not provided, please contact your pharmacist for a replacement.
- QUILLIVANT XR can be taken with or without food. Taking QUILLIVANT XR with food may shorten the time it takes for the medicine to start working.
- From time to time, your doctor may stop QUILLIVANT XR treatment for awhile to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking QUILLIVANT XR.
- Children should have their height and weight checked often while taking QUILLIVANT XR. QUILLIVANT XR treatment may be stopped if a problem is found during these check-ups.
- In case of poisoning call your poison control center at 1-800-222-1222 right away, or go the nearest hospital emergency room.

What are possible side effects of QUILLIVANT XR?

See “**What is the most important information I should know about QUILLIVANT XR?**” for information on reported heart and mental problems.

Other serious side effects include:

- slowing of growth (height and weight) in children

Common side effects include:

- decreased appetite
- weight loss
- nausea
- stomach pain
- dry mouth
- vomiting
- trouble sleeping
- anxiety
- nervousness
- restlessness
- mood swings
- agitation
- irritability
- dizziness
- shaking (tremor)
- blurred vision
- increased blood pressure
- fast heart beat
- increased sweating
- fever

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store QUILLIVANT XR?

- Store QUILLIVANT XR in a safe place at 59°F to 86°F (15°C to 30°C).
- **Keep QUILLIVANT XR and all medicines out of the reach of children.**

General information about the safe and effective use of QUILLIVANT XR

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use QUILLIVANT XR for a condition for which it was not prescribed. Do not give QUILLIVANT XR to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about QUILLIVANT XR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about QUILLIVANT XR that was written for healthcare professionals. For more information, please contact NextWave Pharmaceuticals, Inc., at 1-800-206-8115 or visit the website at www.quillivantxr.com.

What are the ingredients in QUILLIVANT XR?

Active Ingredient: methylphenidate hydrochloride

Inactive Ingredients: sodium polystyrene sulfonate, povidone, triacetin, polyvinol, sucrose, anhydrous trisodium citrate, anhydrous citric acid, sodium benzoate, sucralose, poloxamer 188, corn starch, xanthan gum, talc, banana flavor, and silicon dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for and distributed by:

NextWave Pharmaceuticals, Inc., Cupertino, CA 95014

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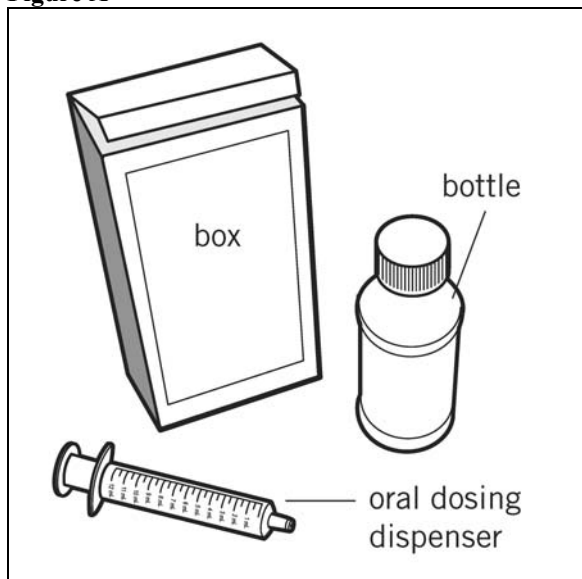
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Instructions for Use
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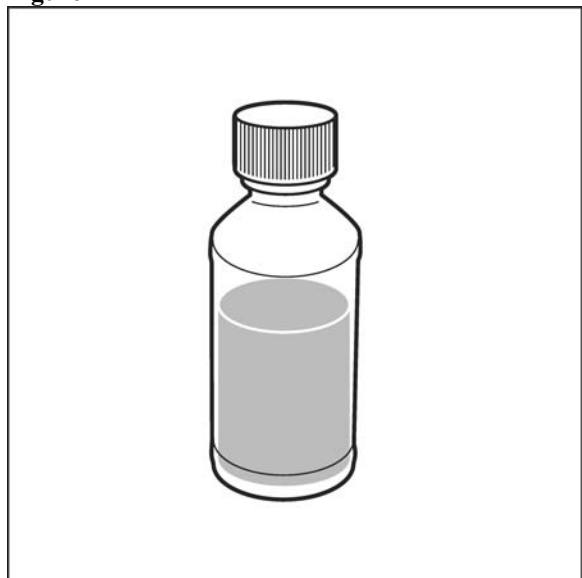
Step 1. Remove the QUILLIVANT XR bottle and oral dosing dispenser from the box (See **Figure A**). If the oral dosing dispenser is missing or not provided, please contact your pharmacist for a replacement.

Figure A



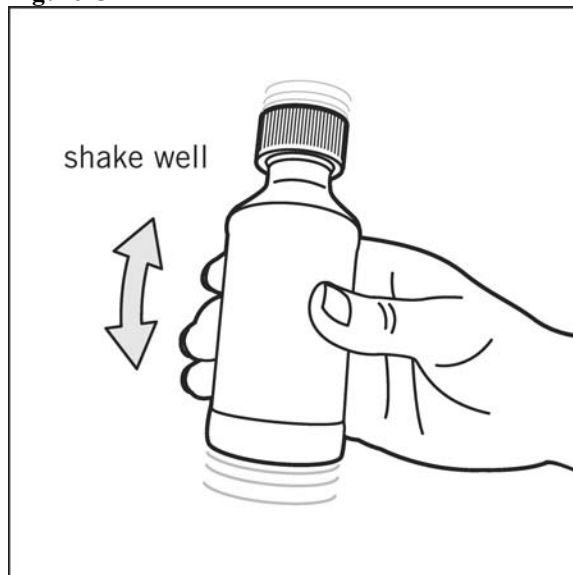
Step 2. Check and make sure that the QUILLIVANT XR bottle contains liquid medicine (See **Figure B**). If QUILLIVANT XR is still in powder form, **do not use it**. Return it to your pharmacist.

Figure B



Step 3. Shake the bottle well (up and down) for at least 10 seconds before each use (See **Figure C**).

Figure C



Step 4. Uncap the bottle and check that the bottle adapter has been inserted into the bottle (See **Figure D**).

Figure D



If bottle adapter (**See Figure E**) has not been inserted into the bottle, insert adapter into the bottle as shown (**See Figure F**).

Figure E

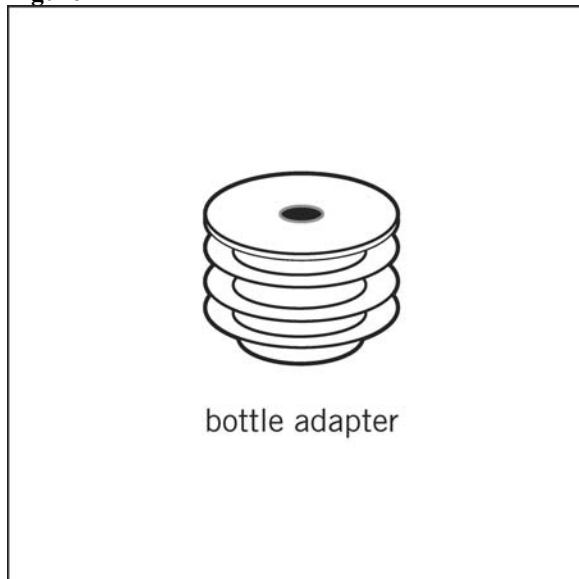
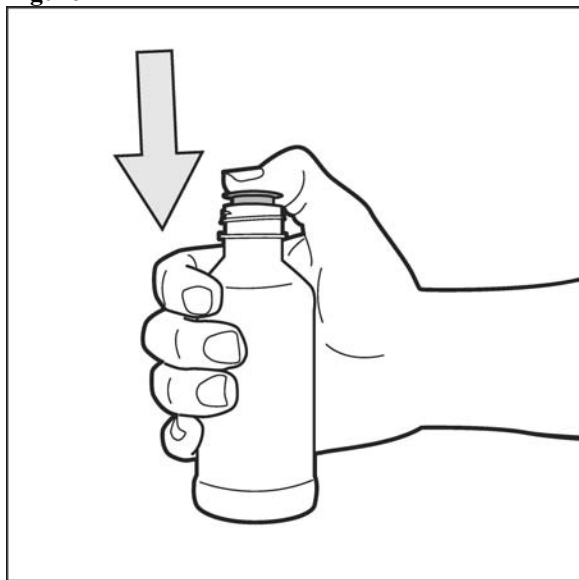


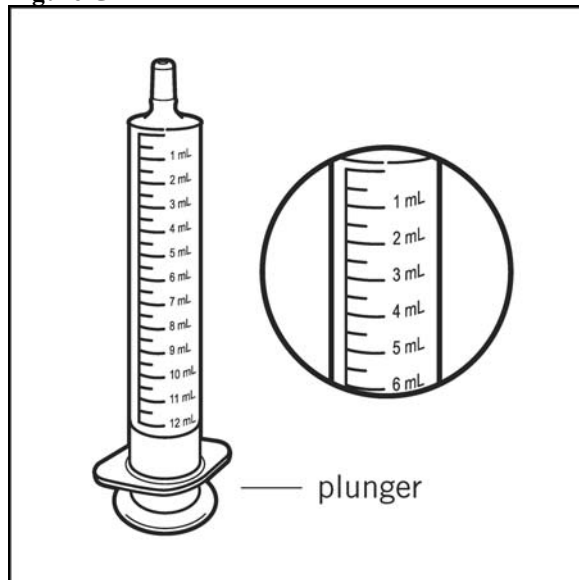
Figure F



Once the bottle adapter has been inserted into the bottle, it should not be removed. If the bottle adapter has not been inserted and is missing from the box, contact your pharmacist.

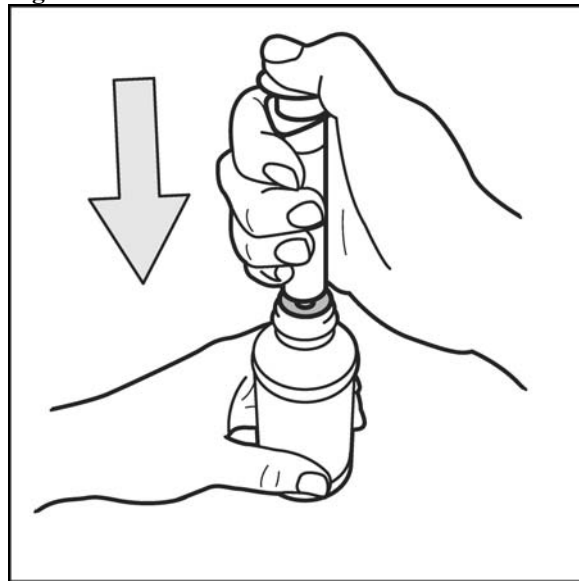
Step 5. Check the QUILLIVANT XR dose in milliliters (mL) as prescribed by your doctor. Locate this number on the oral dosing dispenser (**See Figure G**).

Figure G



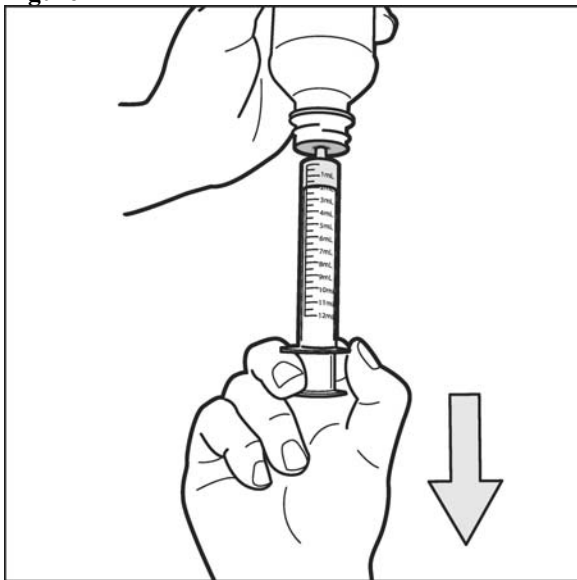
Step 6. Insert tip of the oral dosing dispenser into the upright bottle and push the plunger all the way down (**See Figure H**).

Figure H



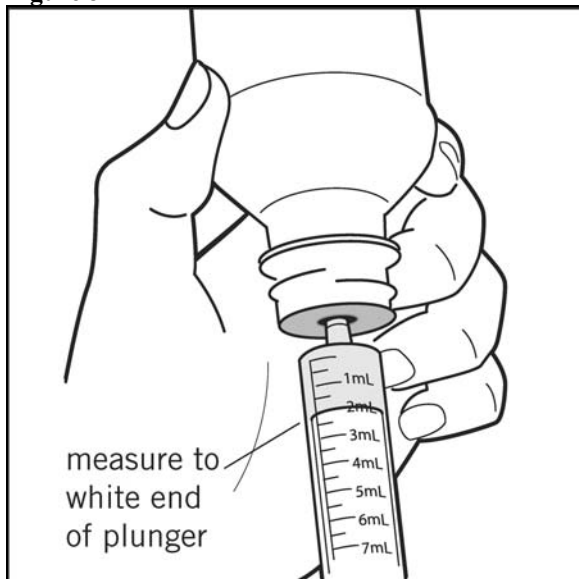
Step 7. With the oral dosing dispenser in place, turn the bottle upside down. Pull the plunger to the number of mL you need (the amount of liquid medicine in Step 5 – See **Figure I**).

Figure I



Measure the number of mL of medicine from the white end of the plunger (See **Figure J**).

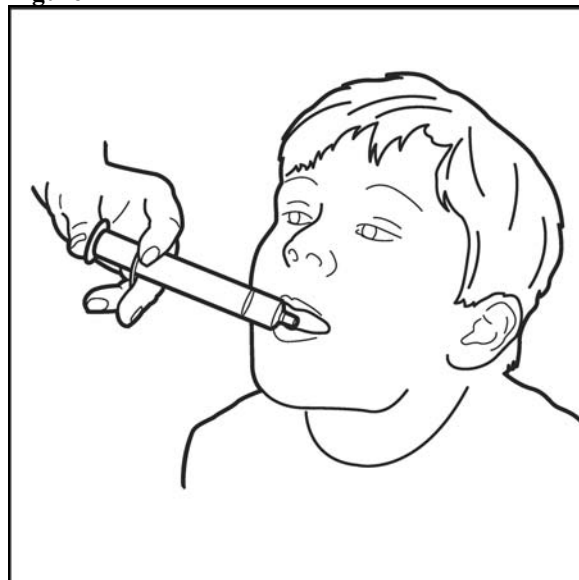
Figure J



Step 8. Remove the oral dosing dispenser from the bottle adapter.

Step 9. Slowly squirt QUILLIVANT XR directly into your or your child's mouth (See **Figure K**).

Figure K



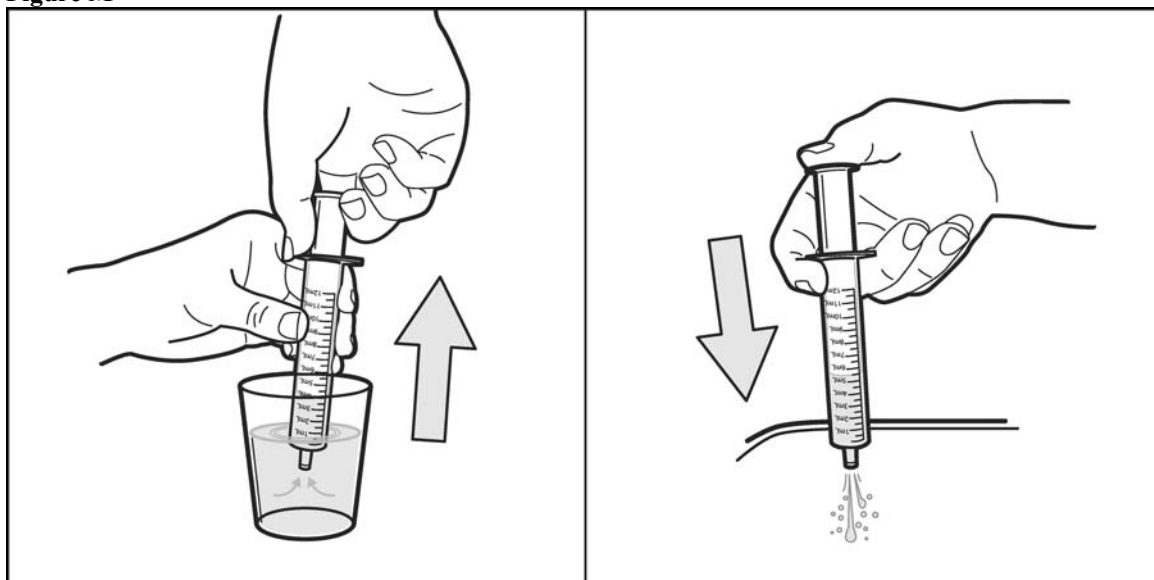
Step 10. Cap the bottle tightly. Store the bottle upright at 59°F to 86°F (15°C to 30°C) (See **Figure L**).

Figure L



Step 11. Clean the oral dosing dispenser after each use by placing in the dishwasher, or by rinsing with tap water (**See Figure M**).

Figure M



These Instructions for Use have been approved by the U.S. Food and Drug Administration.

NextWave Pharmaceuticals, Inc., Cupertino, CA 95014

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